REMARKS

The applicants would like to thank the Examiner for the careful attention given the application in the previous Office Action. Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98 and 112-123 are pending in the application and currently stand rejected. Newly added claims 124-127 are fully supported by the specification as filed, no new matter has been added. Applicants believe the pending claims to be patentable and respectfully request reconsideration and allowance.

35 USC section 102

Claims 1, 16, 31, 54, 70 and 86 stand rejected under 35 USC section 102(b) as anticipated by "Interface Mechanics in Lower-Limb External Prosthetics: A Review of Finite Element Models" by Santosh G. Zachariah and Joen E. Sanders (Zachariah). Applicants respectfully traverse the rejection.

In order to anticipate a claim, a prior art reference must teach all elements of the rejected claim. Claim 1 is directed to a system for analyzing medical devices including a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system and generates a geometric model of said anatomical feature(s). The system includes a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model or mesh representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device. The system also includes a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, loads data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said medical device.

Zachariah is directed to a method for modeling the fit of a prosthetic limb and a patient's residual limb. Zachariah does not disclose or suggest a system with the limitations discussed above with regard to claim 1. In particular, Zachariah does not disclose or suggest a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system and generates a geometric model of said anatomical feature(s). Neither does Zachariah disclose or suggest a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, loads data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction of the vascular system to determine the predicted stresses, strains, and deformations of said medical device.

As such, claim 1 is patentable over Zachariah. Claims 16, 31, 54, 70 and 86 have been amended to include limitations that are the same as or similar to the amendments to claim 1 and are allowable over Zachariah for at least the same or similar reasons as those discussed above.

35 USC section 103

Claims 1-3, 5-7, 9-10, 14, 16-18, 20-22, 24-25, 29, 31-37, 41, 54, 56, 58-60, 62-63, 67-68, 70, 72, 74-76, 78-79, 83-84, 86, 88-92, 96-97 and 112-119 stand rejected under 35 U.S.C. section 103(a) as unpatentable over "Balloon-Artery Interactions During Stent Placement: A Finite Element Analysis Approach to Pressure, Compliance, and Stent Design as Contributors to Vascular Injury" by Campbell Rogers, David Y. Tseng, James C. Squire, and Elazer R. Edelman (Rogers) in view of U.S. Patent No. 5,594,651 to St. Ville (St. Ville). Applicant respectfully traverses the rejection.

In order to establish a prima facia case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. Second, there must be a reasonable expectation of

success for such modification or combination. Finally, the prior art reference or references must teach or suggest all claim limitations. (See MPEP section 2143.03) The motivation to combine or modify a prior art reference in order to make a rejection must be found within the prior art and must not be based on the applicants' disclosure.

Applicants suggest that there is no motivation to combine Rogers with St. Ville, but that even if combined, the combination fails to disclose or suggest all limitations of the rejected claims. As discussed above, claim 1 is directed to a system for analyzing medical devices including a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature of at least one vascular system and generates a geometric model of said anatomical feature(s). The system also includes a mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model or mesh representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device. The system also includes a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, loads data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction of the vascular system to determine the predicted stresses, strains, and deformations of said medical device.

Rogers is directed to two dimensional modeling of the contact stress between a balloon expanded stent and an artery to predict tissue injury from such outward deployment. St. Ville is directed to methods and devices for manufacturing objects having optimized response characteristics and includes a discussion of modeling of a prosthetic hip joint to determine optimization of manufacturing parameters of the prosthetic. As Rogers is directed to modeling contact stress for predicting tissue injury and St. Ville is directed to methods for optimizing manufacturing parameters, there is no motivation to combine the references. However, even if combined, neither reference, alone or in combination, teaches or suggests the limitations of claim 1. In particular, the combination does not disclose or suggest a geometry generator that receives three-

dimensional volumetric data of at least one anatomical feature of at least one vascular system and generates a geometric model of said anatomical feature(s). Neither does Zachariah disclose or suggest a stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, loads data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said medical device.

As such, claim 1 is allowable over the cited references, as are claims 2, 3, 5-7, 9-10, 14 which depend from claim 1. Claims 16-18, 20-22, 24-25, 29, 31-37, 41, 54, 56, 58-60, 62-63, 67-68, 70, 72, 74-76, 78-79, 83-84, 86, 88-92, 96-97 and 112-119 include the same or similar limitations as those discussed above with regard to claim 1 and are allowable over the cited art for at least these same reasons.

Claims 4, 19, 57 and 73 stand rejected under 35 USC section 103(a) as being upatentable over Rogers in view of St. Ville as applied in the previous Office Action to claims 1, 16, 54 and 70, and further in view of U.S. Patent No. 5,880,976 to DiGioia III et al. (DiGioia). As discussed above, there is no motivation to combine Rogers and St. Ville, and even if combined, the combination fails to teach all elements of claims 1, 16, 54 and 70 from which claims 4, 19, 57 and 73 depend, respectively. DiGioia is directed to an apparatus and method for facilitating the implantation of artificial components in joints. As such, DiGioia fails to cure the deficiencies of Rogers and St. Ville and claims 4, 19, 57 and 73 are allowable over the cited references.

Claims 8, 23, 61 and 77 stand rejected under 35 USC section 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 1, 16, 54 and 70 in the previous Office Action and further in view of "Automated Mesh Generation of an Arterial Bifurcation Based Upon In Vivo MR Images" by Seung Lee et al. (Lee). As discussed above, there is no motivation to combine Rogers and St. Ville, and even if combined, the combination fails to teach all elements of claims 1, 16, 54 and 70 from which claims 8, 23, 61 and 77 depend, respectively. Lee is directed to a method of modeling an

interior lumen of an arterial bifurcation for hemodynamic measurements and does not include a mesh of an artery and a device. As such, Lee fails to cure the deficiencies of Rogers and St. Ville and claims 8, 23, 61 and 77 are allowable over the cited references.

Claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 stand rejected under 35 USC section 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 9-10, 24-25, 36-37, 62-63, 78-79 and 91-92 in the previous Office Action and further in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin (Raboin). As discussed above, there is no motivation to combine Rogers and St. Ville, and even if combined, the combination fails to teach all elements of claims 1, 16, 31, 54, 70 and 86 from which claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 depend, respectively. Raboin describes some current problems that various finite element analysis methods are being used to solve. Although Raboin discusses a process for acquiring human data for modeling human joints, Raboin does not teach or suggest simulating an interaction between anatomical feature(s) and a medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data. As such, Raboin fails to cure the deficiencies of Rogers and St. Ville and claims 11-12, 26-27, 38-39, 64-65, 80-81 and 93-94 are allowable over the cited references.

Claims 15, 30, 42, 69, 85, and 98 stand rejected under 35 USC section 103(a) as being upatentable over Rogers in view of St. Ville as applied to claims 14, 29, 41, 68, 84, and 97 in the previous Office Action and further in view of "GRIZ Finite Element Analysis Results Visualization for Unstructured Grids User Manual" by Douglas E. Speck and Donald J. Dovey (Dovey). As discussed above, there is no motivation to combine Rogers and St. Ville, and even if combined, the combination fails to teach all elements of claims 1, 16, 31, 54, 70 and 86 from which claims 15, 30, 42, 69, 85, and 98 depend, respectively. Dovey is a users manual for finite element analysis using unstructured grids and does not discuss modeling of an anatomical feature or simulating an interaction between anatomical feature(s) and a medical device over at least one

dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data. As such, Dovey fails to cure the deficiencies of Rogers and St. Ville and claims 15, 30, 42, 69, 85, and 98 are allowable over the cited references.

Claims 55, 71, 87, and 120-123 stand rejected under 35 USC section 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 54, 70 and 86 in the previous Office Action and further in view of "Failure of All-ceramic Fixed Partial Dentures in vitro and in vivo: Analysis and Modeling" by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen). As discussed above, there is no motivation to combine Rogers and St. Ville, and even if combined, the combination fails to teach all elements of claims 54, 70 and 86 from which claims 55, 71, 87, and 120-123 depend, respectively. Dovey is a users manual for finite element analysis using unstructured grids and does not discuss modeling of an anatomical feature or simulating an interaction between anatomical feature(s) and a medical device over at least one dynamic expansion and contraction cycle of the vascular system to determine the predicted stresses, strains, and deformations of said candidate medical device design by said load data. As such, Dovey fails to cure the deficiencies of Rogers and St. Ville and claims 55, 71, 87, and 120-123 are therefor allowable over the cited references.

Regarding newly added claims 124-127, these are dependent claims which are allowable over the cited art for at least the reasons discussed above with regard to the respective independent claims from which they depend. To the extent applicable, the discussion above is incorporated here with regard to claims 124-127. In addition, claims 124-127 include limitations that are not disclosed or suggested in the cited art.

In view of the foregoing, Applicant believes the pending claims to be patentable. Reconsideration and early allowance is sincerely requested.

Respectfully submitted,

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